510 K summary K120558

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Device Trade Name	OneTouch Reveal Diabetes Management Application
Common Name	Diabetes Management Software
Classification	NBW - system, test, blood glucose, over the counter 862.1345 Glucose test system. Class II JQP - Calculator/data processing module for clinical use 862.2100 Calculator/data processing module for clinical use. Class I subject to limiations 862.9 (c)(5) For use in diabetes management

System Description	The OneTouch® Reveal Diabetes Management Application (App) is a diabetes management tool that can help you determine what your blood glucose test results mean. This allows you and your health care professional to better monitor and adjust your diabetes care plan. The App is designed to work in conjunction with the OneTouch® Verio™ Sync Meter. Using the Bluetooth® feature on your meter and Apple® device, blood sugar test results can be sent directly from your meter to the App. Once a blood sugar result is sent to the App you can: • Tag the blood sugar result with a meal flag, • Receive Low and High Pattern messages, • Add carbs, activity, medication data and Notes about your activities, • Manually enter other blood sugar test results, • Review results on graphs, • Share your blood sugar results with others for review and follow-up, and • Set reminders to prompt you to complete certain tasks.
Predicate Device	DiabetesManager® System, WellDoc, Inc. (K100066)
Intended Use/Indications for Use	The OneTouch® Reveal Diabetes Management Application is a software accessory to the OneTouch® Verio Sync Blood Glucose Monitoring System, and is intended for use in the home setting by people with diabetes. It is intended to aid in the review, analysis, and evaluation of patient data to support diabetes management. The OneTouch® Reveal Diabetes Management Application receives (from both manual

	entry and wireless transmission), stores, and sends patient data for display and reporting. The OneTouch® Reveal Diabetes Management Application also communicates with web-based applications. The OneTouch® Reveal Diabetes Management Application is available for use on commercially-available mobile devices and uses generally-available networks and communication protocols.
Comparison to Predicate Device	The OneTouch® Reveal Diabetes Management Application incorporates similar technology and functionality provided by the DiabetesManager System including; • Capture, storage and transmission of patient data; • Analysis and reporting of blood glucose results to aid in blood glucose management; • Entry of diabetes related information to aid in diabetes self-management; Unlike the predicate, the OneTouch® Reveal Diabetes Management Application has a software feature that alerts users to low and high blood glucose patterns. This software feature has also been implemented on another cleared LifeScan blood glucose meter, the OneTouch Verio IQ Blood Glucose Meter, K110637.

Technological Characteristics	The OneTouch® Reveal™ Application is designed to run under Apple iOS 4+ operating systems on the following devices: • iPhone 4 and iPhone 3GS • iPod Touch 3rd and 4th Gen • iPad 1st and 2nd Gen The App stores blood glucose test results, events and user settings. The App's memory capacity is 2500 blood glucose results and events; and is limited to a maximum of 1 year of results and events. In addition to receiving blood glucose measurement readings from the OneTouch Verio Sync Meter via Bluetooth, storing and displaying them, the App provides the following features and tools for the user: • Time Synchronization: Synchronizing the time between the App and the OneTouch Verio Sync Meter. • Tagging of Results: Allows quick settings of meal tags and notes to results just downloaded from the meter. • Pattern Messages: Alerts the user that one or more patterns were found in the results that were downloaded. • Events: Allows the user to manually enter data, such as: manual blood glucose results, carbohydrates consumed, activity performed and medications taken. • Sharing: Allows the user to share blood glucose results via SMS text or eMail.

	• Summary: Allows the user to view results in summary in the following ways: 14-day Glucose Report, last meter "Sync" results and patterns, "Today" results & events. • Logbook: Allows the user to view results by date and time-slot, 14-day graph, time-of-day graph. • Pattern Recognition: Alerts the user of Low patterns and Before-Meal High patterns detected in the last 14-days and allows review of those patterns and their details. • More: Allows the user to personalize/customize the App through the following: "About Me" personal settings, "General" application options, "Reminders", "Help", and "Contact OneTouch" information.

Summary of Performance Characteristics	Full verification and validation testing of the OneTouch® Reveal™ Diabetes Management Application software was performed in accordance with the FDA Guidance Document 'General Principles of Software Validation (2002)'. A user performance evaluation study was conducted to validate the OneTouch® Reveal Diabetes Management Application. Human Factors Formative Usability studies were also conducted to evaluate the usability of the OneTouch Reveal Diabetes Management Application and to inform final design of the product.

Conclusions

The OneTouch Reveal Diabetes Management Application is substantially equivalent in its intended use, performance, safety, effectiveness and underlying scientific and operating principles used to the predicate, the DiabetesManager® System, WellDoc, Inc. (K100066).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 7, 2013

Lifescan, Inc.
c/o Andrea M. Tasker
Director, Regulatory Affairs
200 Lawrence Drive
Mailstop C-5-1
West Chester, PA 19380

Re: k120558
Trade/Device Name: OneTouch® Reveal Diabetes Management Application
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, JQP
Dated: January 22, 2013
Received: January 24, 2013

Dear Ms. Tasker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k120558

Device Name: OneTouch® Reveal Diabetes Management Application

Indications for Use:

The OneTouch® Reveal Diabetes Management Application is a software accessory to the OneTouch® Verio Sync Blood Glucose Monitoring System, and is intended for use in the home setting by people with diabetes. It is intended to aid in the review, analysis, and evaluation of patient data to support diabetes management. The OneTouch® Reveal Diabetes Management Application receives (from both manual entry and wireless transmission), stores, and sends patient data for display and reporting. The OneTouch® Reveal Diabetes Management Application also communicates with web-based applications. The OneTouch® Reveal Diabetes Management Application is available for use on commercially-available mobile devices and uses generally-available networks and communication protocols

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use __X__ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Katherine Serrano

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k120558